DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-000

October 29, 2015

American Orthodontics
Ms. Trang Adams
Regulatory Affairs Specialist
3524 Washington Avenue
Sheboygan, WI 53081

Re: K143117
Trade/Device Name: Wire Sterilization Package with Indicators
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG; JOJ
Dated: September 21, 2015
Received: September 29, 2015

Dear Ms. Adams,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
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Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
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Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143117

Device Name
Wire Sterilization Package with Indicators

Indications for Use *(Describe)*
Wire Sterilization Package with Indicators is intended to be used to enclose and package American Orthodontics' line of Orthodontic Arch Wires. These packages are shipped unsterile and for single-use only. This packaging offers the health provider (trained dental professional and/or Orthodontist) the option of sterilizing the enclosed arch wire using steam or ethylene oxide gas. The indicators will display a visual color change to signify exposure to steam or ethylene oxide gas and distinguish between processed and unprocessed wire.

STERILIZATION PARAMETERS
Ethylene Oxide [100% E.O.] Gas

1. EO Concentration: 725 mg/L
2. Exposure Temperature: 130°F (55°C)
3. Exposure Time: 1 hour
4. Aeration Time: 8 hours

Upon completion of the process, the EO color indicator will change from Blue to Cocoa Brown.

Steam – Gravity

1. Exposure Temperature: 270°F (132°C)
2. Exposure Time: 15 minutes
3. Dry Time: 30 minutes

Upon completion of the process, the STEAM color indicator will change from Blue to Black/Brownish Black.

Please Note: Upon completion of the process, the archwire is to be used immediately.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

21CFR807.92

Date Prepared: October 23, 2015

Company Information:

American Orthodontics
3524 Washington Avenue
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Phone: 920-457-5051
Fax: 920-457-5773

Contact Information:

Trang Adams / Regulatory Affairs Specialist

Device Information:

Trade Name: Wire Sterilization Package with Indicators
Common Name: Wire Sterilization Package with Indicators
Classification Name: Sterilization Wrap; Sterilization Process Indicator
510(k) Number: K143117
Classification Code: FRG; JOJ
Regulation Number (21CFR): 880.6850; 880.2800

Component Device Information:

Common Name: Orthodontic Arch Wires
Classification Name: Wire, Orthodontic
510(k) Number: Exempt (Class I)
Classification Code: DZC
Regulation Number (21CFR): 872.5410
American Orthodontics' Models: Stainless Steel Wires, Nickel Titanium (NiTi) Wires, Beta Titanium Wires, Chromium Cobalt (CrCo) Wires, Copper Nickel Titanium (CuNiTi) Wires

Predicate Devices Information:

Primary Predicate:

Product/Trade Name: Safe Secure Sterilization Pouch with Steam and Ethylene Oxide Process Indicators
Manufacturer: Safe Secure Packaging Company, Limited
510(k) #: K112591
Classification Name: Sterilization Wrap
Classification Code: FRG
Regulation Number (21CFR): 880.6850

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Secondary Predicate:

Product/Trade Name: Cross-Checks Indicator
Manufacturer: SteriTec Products Mfg. Co., Inc
510(k) #: K951113
Classification Name: Sterilization Process Indicator
Classification Code: JOJ
Regulation Number (21CFR): 880.2800

American Orthodontics' new device combines a sterilizable pouch (Classification Code: FRG) with sterilization process indicators (Classification Code: JOJ) that contains an Arch Wire (Classification Code: DZC). It was deemed appropriate to choose two predicates containing the classification codes that were suitable to the Wire Sterilization Package with Indicators to demonstrate substantial equivalency.

Description of the Device:

American Orthodontics' Wire Sterilization Package with indicators is manufactured from bleached surgical paper and plastic film with external chemical process indicators. This packaging is a pouch that is enclosed on all four sides and contains a single arch wire. These packages are shipped unsterile and for single-use only. This packaging offers the health provider (trained dental professional and/or Orthodontist) the option of sterilizing the enclosed arch wire using steam or ethylene oxide gas. Upon completion of the sterilization process, the enclosed arch wire is intended to be used immediately.

This packaging is not offered as a stand-alone product, but is strictly used for the packaging of American Orthodontics' Arch Wires (Classification Code: DZC; 510(k) Exempt).

The bleached surgical paper conforms to the FDA 21CFR186.1673 and can be sterilized using steam or ethylene oxide gas.

The plastic film is sealed to the bleached surgical paper and conforms to 21CFR177.1630 (Polyester), 21CFR175.105 (Adhesive) and 21CFR177.1520 (Polypropylene).

The process indicators meet the performance requirements of AAMI/ANSI/ISO 11140-1:2014.

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Indications for Use:
Wire Sterilization Package with Indicators is intended to be used to enclose and package American Orthodontics' line of Orthodontic Arch Wires. These packages are shipped unsterile and for single-use only. This packaging offers the health provider (trained dental professional and/or Orthodontist) the option of sterilizing the enclosed arch wire using steam or ethylene oxide gas. The indicators will display a visual color change to signify exposure to steam or ethylene oxide gas and distinguish between processed and unprocessed wire.

STERILIZATION PARAMETERS
Ethylene Oxide [100% E.O.] Gas

1. EO Concentration: 725 mg/L
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4. Aeration Time: 8 hours

Upon completion of the process, the EO color indicator will change from Blue to Cocoa Brown.

Steam – Gravity

1. Exposure Temperature: 270°F (132°C)
2. Exposure Time: 15 minutes
3. Dry Time: 30 minutes

Upon completion of the process, the STEAM color indicator will change from Blue to Black/Brownish Black.

Please Note: Upon completion of the process, the archwire is to be used immediately.

The Indications for Use statement for American Orthodontics' Wire Sterilization Package with indicators is not identical to the predicates however, the differences do not alter the intended use or safety and effectiveness of the device relative to the predicates. Both devices have the same intended use, to be able to distinguish between processed and unprocessed devices.

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Device Comparison:

For detailed comparisons, please reference Section 12: Substantial Equivalence Discussion.

The table below outlines comparisons of the predicates and American Orthodontics' Wire Sterilization Packaging with Indicators to show substantial equivalency.

	Device Name / Manufacturer			
Element	**Safe Secure Sterilization Pouch with Steam and Ethylene Oxide Process Indicators / Safe Secure Packaging Company, Limited**	**Cross-Checks / SteriTec Products Mfg. Co., Inc**	**Wire Sterilization Packaging with Indicators/ American Orthodontics**	**Substantial Equivalence Analysis**
510(k) Number	K112591	K951113	K143117	N/A
Classification Code/ Regulation Number	FRG 880.6850	JOJ 880.2800	FRG/JOJ 880.2800/880.6850	N/A
Intended Use	Safe Secure Sterilization Pouch with Steam and Ethylene Oxide Process Indicators Models: ABHSP, ABSSP, is intended to be used to enclose another medical device that is to be sterilized by a health provider by gravity steam and ethylene oxide (EtO). The recommended steam sterilization cycle parameters are 30 minutes at 121°C (250°F). The recommended EtO gas sterilization cycle is 735mg/L of ethylene oxide (EtO) for 1 hour at 55°C (130°F) and 50% to 80% RH. The pouch's external chemical ink indicators on the pouches are intended to demonstrate that the device has been exposed to steam or EtO sterilization process and to distinguish between processed and unprocessed devices. The pouch is intended to allow sterilization of the enclosed medical device.	SteriTec CROSS-CHECKS sterilization chemical monitoring strips are designed to be utilized in steam sterilizer operating at 132°C to 135°C (270°F to 276°F). When used as directed, the SteriTec Cross-Checks indicator strips give visible indication that sterilizing conditions were met. During steam sterilization, the check mark at the end of the strip changes from white to black, becoming as dark or darker in intensity than the black reference arrow printed on the strip.	Wire Sterilization Package with Indicators is intended to be used to enclose and package American Orthodontics' line of Orthodontic Arch Wires. These packages are shipped unsterile and for single-use only. This packaging offers the health provider (trained dental professional and/or Orthodontist) the option of sterilizing the enclosed arch wire using steam or ethylene oxide gas. The indicators will display a visual color change to signify exposure to steam or ethylene oxide gas and distinguish between processed and unprocessed wire.	Equivalent
Device Design & Components	**Pouch:** 2-30" Wx2-30"L, Medical-grade paper or Tyvek, Plastic Film **Chemical Indicator:** not disclosed; printed on surgical paper	**Strip:** 0.5625"W x 7.66" L, 80 lbs Cover **Chemical Indicator**: White to Dark; printed on paper strip over laminate of PET	**Pouch:** 3.5" Wx4.5"L, 60g/m² Surgical Paper, Blue Film **Chemical Indicator:** Steam: Blue to Brownish Black/Black; Ethylene Oxide: Blue to Coco Brown	Equivalent
Indicator Agent	**Indicating Ink:** Proprietary to Safe Secure, yields a color-change	**Indicating Ink:** Lead based agent to yield color-change	**Steam Indicating Ink:** Lead based agent to yield color-change **Ethylene Oxide Indicating Ink:** Water based agent to yield color-change	Equivalent
Sterilization Methods	**Steam**: 121°C for 30 minutes. **Ethylene Oxide gas :** 55°C for 1 hour	**Steam:** 132°C - 134°C for 3 minutes	**Steam**: 132°C for 15 minutes **Ethylene Oxide**: 55°C for 1 hour	Equivalent
Standards Met	ISO 11140-1 (Indicators)	ISO 11140-1 (Indicators)	ISO 11140-1 (Indicators)	Equivalent

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Performance Data:
Please reference Section 15: Biocompatibility and Section 18: Performance Testing - Bench for more details.

The following performance data were provided:

MATERIAL COMPATIBILITY TESTING
Material Compatibility Testing for the enclosed arch wires were conducted following ISO 15841:2014 Dentistry – Wires for Use in Orthodontics before and after the sterilization processes. Sterilization of the arch wires using Steam, Formaldehyde and Ethylene Oxide had no effect on the material or functionality of the arch wires.

PERFORMANCE TESTING
Performance Testing was conducted by placing spores in the most difficult to sterilize locations. Samples were processed at half cycle and biological indicators (BI) removed after exposure. Biological indicators were aseptically transferred to culture media and incubated. Performance testing validated that the cycles are able to achieve the desired Sterility Assurance Level (SAL).

RESIDUAL TESTING
Residual testing was conducted following ISO 10993-7:2008/(R) 2012 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals. Test samples met reference guidelines.

INDICATOR VALIDATION
Indicator Validation testing was conducted following AAMI/ANSI ISO 11140-1 Sterilization of Health Care Products – Chemical Indicators – Part 1: General Requirements. Results verified that the chemical indicators tested changed to an appropriate signal color when tested under the "Pass Cycle" conditions and met the "Pass Cycle" requirements for Class I process indicators.

BIOCOMPATIBILITY/LEACHABILITY: CYTOTOXICITY TESTING
Cytotoxicity Testing was conducted after sterilization processes following ISO 10993-5: Biological Evaluation of Medical Devices – Part 5: Tests for In-Vitro Cytotoxicity and United States Pharmacopeia/National Foundry, <87> Biological Reactivity Test, In Vitro; Elution Test. American Orthodontics' Wire Sterilization Package with Indicators do not come into contact with patients. The enclosed archwires met the USP and ISO 10993-5 requirements for the test. All test samples **PASSED.**

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BIOCOMPATIBILITY – (ENCLOSED ARCHWIRES)

Archwires were sent to independent labs for biocompatibility testing before sterilization according to ISO 10993-5:2009, Biological Evaluation of Medical Devices – Part 5: Tests for *In Vitro* Cytotoxicity and ISO 10993-10, Tests for Irritation and Sensitization – Sensitization Test. All test samples **PASSED**.

Biocompatibility Justification for stainless steel archwires is included in Section 15: Biocompatibility.

Summary:

The Wire Sterilization Package with Indicators is provided as a convenient and purely optional method for the trained dental professional and/or Orthodontist to sterilize American Orthodontics' arch wires. This does not affect the function of the enclosed arch wires, nor does it affect the original purpose of the package – which is to store and ship individual arch wires.

Conclusion:

American Orthodontics' Wire Sterilization Package with Indicators has the following similarities to those legally marketed under 510(k) numbers K112591 (Primary Predicate) and K951113 (Secondary Predicate):

- Same intended use; and
- Same technological characteristics through device design, indicator agent, sterilization method and incorporation of similar materials.

Generated testing data in accordance to "ANSI/AAMI/ISO 11140-1:2014 Sterilization of health care products – Chemical indicators" demonstrates that the indicators on American Orthodontics' Wire Sterilization Package with Indicators are substantially equivalent to the predicate devices.

Any slight differences do not affect the original function or intended purpose of the device.

Information contained in this 510(k) does not raise new questions or safety and effectiveness, and, demonstrates it is at least as safe and effective as the listed predicates.